Protocol

Physical Activity and Sedentary Behaviour in Patients with Inflammatory Bowel Disease - epidemiology and interventions (PASIBO)

NCT number: Not yet assigned

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Introduction

Emerging research suggests that physical activity may improve health-related quality of life (HrQoL) in patients with inflammatory bowel disease (IBD) and positively influence physical symptoms, fatigue, stress and anxiety (1). However, little is known about detailed movement patterns and their specific health effects in IBD patients or about patients' wishes, motivation and preferences for physical activity in their everyday lives. Future interventions approaches may have more success if they consider the variability in patients' symptoms, circumstances, social resources and lifestyles. Previously, we have conducted RCT studies in patients with rheumatoid arthritis (RA), which showed positive effects on objectively measured physical activity and sedentary behaviour, cardiometabolic biomarkers, pain and HrQoL of an individually tailored, theory-based behavioural intervention with motivational counselling and text message reminders to increase everyday physical activity and reduce sedentary behaviour (2). RA is a chronic autoimmune disease with many similarities with IBD with respect to disease manifestations and medical treatment. Therefore, a similar approach may be feasible in patients with IBD as well. Considering the lack of solid evidence on the potential implications and significance of physical activity and sedentary behaviour in patients with IBD, we propose to conduct a combination of both epidemiology and intervention studies.

Background

Inflammatory bowel disease

Inflammatory Bowel Disease (IBD) is characterized by chronic inflammation of the intestines. The aetiology of IBD is not fully identified, but it appears to be multifactorial and influenced by an abnormal immune response to gut microbes in genetically predisposed persons (3). The two most common types of IBD are Crohn's disease (CD) and Ulcerative Colitis (UC). In Denmark, the incidence is 9/100.000 per year for CD, and 19/100.000 for UC (4). In both types of IBD the incidence is highest among young adults and approximately 53.000 patients are living with IBD in Denmark (4). IBD is characterized by periods of remissions and relapses. Symptoms include diarhea, abdominal cramps and pain, rectal bleeding, weight loss, and potentially extraintestinal manifestations involving joints, skin and eyes. These symptoms are often accompanied by further health problems, such as reduced bone mineral density and osteoporosis, fatigue, depression and reduced physical fitness (1,5,6). The latter may be caused by the disease itself, as a side effect of the medical treatment and/or by an inadequate level of physical activity. Consequently, the physical IBD symptoms may impact negatively on patients' psychological and social well-being, and thus,

lead to impaired health-related quality of life (HrQoL) (7). Further, patients with IBD tend to have a low educational level and diminished social functioning (8).

Treatment of IBD

Lifelong medical treatment for IBD is often necessary and include corticosteroids, aminosalicylates, immunosuppressants and biologics. The main goal in the treatment of IBD is to obtain clinical remission by reduction of the extent and severity of inflammation, which also reduces the risk of colon cancer associated with long term inflammation (3). Treatment may relieve symptoms, but undesirable side effects are common. A large proportion of patients also undergo surgery with removal of affected bowel segments, and/or temporary or permanent stoma formation (9). The cumulative incidence for surgery is 50-80 %, somewhat higher in patients with CD than among patients with UC.

Physical activity and sedentary behaviour in patients with IBD

Many patients seek supportive and adjunctive therapies, and the existing literature suggests that physical activity and exercise may counteract physical symptoms, fatigue, stress and anxiety, and improve HrQol in patients with IBD (3). Although patients with IBD seem to benefit from physical activity and exercise they may also experience considerable barriers to exercise, of which IBD-related barriers such as fatigue, abdominal pain and physical weakness are dominant (10,11). In a recent cross-sectional study (N=306) up to two-thirds of patients with IBD reported that the IBD limited the amount of physical activity undertaken (11). Also, feelings of embarrassment and shame (in case of stoma) may act as barriers to regular exercise and vigorous physical activity in patients with IBD (10). Accordingly, this calls for a wider approach in promoting physical activity in this group of patients, which include not only a focus on increasing moderate to vigorous physical activity and exercise but also a focus on everyday movement and reduction of sedentary behaviour among patients with IBD. Sedentary behaviour, defined as 'any waking behaviour characterised by an energy expenditure of ≤1.5 metabolic equivalents of task while in a sitting, reclining or lying posture' (12) has been increasingly studied in populations with chronic diseases during the last decade (13,14). While recent epidemiological research has shown linear dose-response associations of sedentary behaviour (> 6 h/day) with the development of IBD, statistically independent of physical activity (15), little research attention has been given to levels of sedentary behaviour and associations with symptoms, disease activity and other health outcomes in patients with already established IBD. Altogether, this supports the need to investigate and address sedentary behaviour as well as physical activity and exercise in future research and interventions that promote physical activity in patients with IBD.

Physical activity interventions in patients with IBD

Although existing literature indicates potential health benefits of physical activity and exercise in patients with IBD, there is little consistency in the proposed interventions for promoting physical activity (1), and large variations in the applied physical activity intensities and types in the existing exercise or physical activity intervention studies (1). For instance, the studied types of interventions have ranged from yoga and tai-chi to walking programs, outdoor running programs and resistance training (1). The heterogeneity of intervention methods and intensities does not allow for solid conclusions about the most appropriate type of exercise and physical activity for patients with IBD. In addition, we know very little about the patients' needs, motivation and preferences for sedentary behaviour, physical activity and exercise in their everyday lives. As such, a 'one size fits all' physical activity intervention approach may have limited success because of the variability between the patients' settings, social resources, and lifestyles (7). Rather, an individual approach, where the patient's individual resources and opportunities for increasing daily movement are identified, discussed and used actively in the intervention may be more encouraging and effective on symptoms and quality of life for patients with IBD - and not least, empower more sustainable changes in the patients' physical activity levels. Anticipating that reducing sedentary behaviour and replacing it with light-intensity physical activity would be more feasible and accessible in patients with physical symptoms and limitations (16), we recently investigated a such individual approach on physical activity behaviour and symptoms in patients with rheumatoid arthritis (RA). In a randomized controlled trial we found convincing effects on objectively measured physical activity and sedentary behaviour, cardiometabolic biomarkers, pain and HrQoL of an individually tailored, theory-based behavioural intervention with motivational counselling and text message reminders (2,17,18). IBD has many similarities with RA with respect to disease manifestations and progression. While RA primarily causes inflammation in the joints and IBD inflammation in the intestines, both diseases are characterized by flares and fluctuating disease activity, and by accompanying symptoms and problems such as severe fatigue, reduced bone mineral density, osteoporosis, low physical fitness and an impaired HrQol. Therefore, a similar individual approach addressing daily movement in a 24-hour perspective may be feasible and effective in patients with IBD as well. In fact, it may be even more appropriate in patients with IBD as this group of patients is heterogenetic in terms of differences in age, disease site (in intestines), symptoms and disease severity with some patients operated (stoma) and others, who are in clinical remission.

To sum up, although patients with IBD seem to benefit from increasing physical activity and exercise, they experience barriers to engaging in physical activity that are related to both stigmatization and disease symptoms. These are barriers that might be overcome if the physical intervention is focusing on variation in

physical activity intensity and is tailored to the individual patient. However, we know little about the specific needs and preferences of the patients, which we wish to explore through developing the intervention in collaboration with patients and other relevant stakeholders. We hypothesise that an individually tailored intervention focusing on physical activity in a 24-hour perspective, including sedentary behaviour and physical activity from light to vigorous intensity, is feasible and effective in patients with IBD

Aims

The overall aim of the project is to develop and test an evidence-based personalized intervention for promotion of physical activity and reduction of sedentary behavior in patients with IBD. The overall project also includes an ongoing epidemiological part (Part I – studies I and II) besides the present intervention part (Part II – studies III and IV).

Intervention (Part II)

Based on the knowledge obtained in the epidemiological studies (Part I), we will

1. develop an intervention for the promotion of physical activity and reduction of sedentary behavior in patients with IBD through a co-creation process in collaboration with the patients and other stakeholders using a systems approach (**Study III**)
2. test the feasibility of the developed intervention, with respect to recruitment, retention, adherence and acceptability (**Study IV**)

In the following, only the design and methods for study IV, the feasibility study, will be described.

Methods

Study IV. Feasibility study

Design

Study IV is a feasibility study testing the developed intervention for feasibility and acceptability in a small sample (N=30) of patients with IBD from the gastroenterology outpatient clinic at Bispebjerg Hospital, Copenhagen. By conducting a feasibility study with a small sample size, we want to follow the course of an intervention that has been developed as an individual offer with possibilities and solutions for the individual patient, but still operated within a controlled and standardized research frame. Thus, before testing the intervention in a large-scale randomized controlled trial, we need to evaluate whether this model is applicable in the patients and their individual settings. Assessment of feasibility will include identification of barriers for recruitment, acceptance of group/randomization status, delivery methods, retention, outcome assessments and logistics using qualitative and quantitative methods for process evaluation (19).

In – and exclusion criteria

The inclusion criteria for patients:

- A diagnosis of IBD (Crohn's disease or ulcerative colitis) > 1 year
- > 18 years of age
- Minimum three months stable medication type and dose without use of steroids as part of the medical treatment during the last three months
- Speak and understand Danish

The exclusion criteria for patients:

- Unable to give informed consent
- Active inflammatory disease in joints, skin, pancreas, thyroid, lungs or liver that can hinder engagement in physical activity and exercise
- Cognitive and/or mental disabilities that can hinder engagement in physical activity and exercise
- Engaging in high-intensity physical activity -/> 8 hours pr week

Recruitment

Patients for the feasibility study will be recruited from the gastroenterology outpatient clinic at Bispebjerg Hospital, Copenhagen. Patients will be identified and invited by nurses and physicians at the outpatient clinic, who will describe the project and provide patients with written information about the project. If identified patients are willing and eligible to participate according to in – and exclusion criteria, the outpatient clinic staff will pass on the patients' contact details to intervention leader, TT, or a project nurse, employed at the gastroenterology department. Either TT or the project nurse will then contact the patients by telephone and invite them and a relative (if wished for) to an information meeting at the gastroenterology department. Here, the patients will receive oral information on the project by TT in a private room. This information will include the purpose, methods, time frame and possible risks of participating with sufficient time for the patients to understand and ask questions. Furthermore, the patients will be informed about the possibility of declining any new information on their health status that may emerge during the study, and additionally, the possibility to withdraw their consent at any time without it affecting their current treatment in the clinic. If patients decide to participate in the study during the information meeting, they will sign a written consent. However, patients will also be offered 48 hours

to reflect and decide on participation or not. Either TT or the project nurse will then obtain their signed consent at a later stage in the clinic.

Randomization and blinding

Study participants will be randomly assigned (1:1) to either an intervention group (n=15) or a control group (n=15). The randomization will be conducted through the REDCap (Research Electronic Data Capture) platform (see description under 'data management'). The allocation sequence will be concealed from the project leaders. It will not be possible to blind participants and project staff delivering the intervention to allocation status, whereas all outcome data will be collected by blinded outcome assessors.

Intervention

The intervention is an individually tailored, behavioural intervention addressing the individual patient's knowledge, motivation, resources and opportunities for increasing daily physical activity in the individual's everyday life.

The 20-week intervention will consist of a basic part for all participants, which will include

1) A group session with education about IBD in general and about physical activity and exercise in relation to IBD (definitions, evidence and recommendations). Following this session, the participants will also be offered access to a video with general information about IBD, physical activity and exercise
2) Four individual motivational counselling sessions (two physical and two telephone sessions) with a project nurse. The counselling sessions will involve identifying the individual's motivation and opportunities for increasing physical activity, behavioral goal setting and action planning.

An optional intervention part will then follow, where the individual participant will have the possibility of choosing between (or all of)

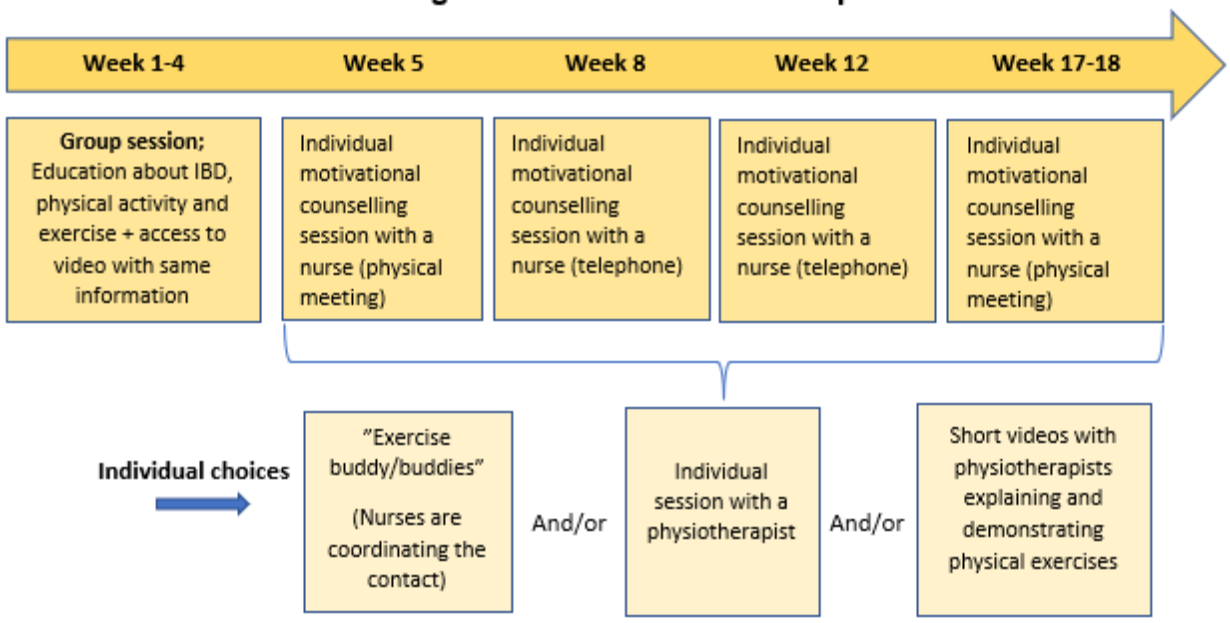
1) A one-hour individual session with a physiotherapist from Bispebjerg/Frederiksberg Hospitals, which will involve guidance in physical activity and exercise tailored to the individual participant. This could be the case if a participant experiences specific symptoms or limitations when engaging in physical activity and/or exercise and needs individual guidance related to this.
2) Being teamed up with 1-2 'exercise buddies' (other participants from the overall intervention group). During the intervention development phase stakeholders (patients with IBD) argued for the possibility of being physically active/exercising with others in small groups to increase motivation

and sustain physical activity behaviour, which is why we would like to offer this as an optional element of the intervention.

3) Access to 5-10 short 2-3 minutes videos/'reels' of a physiotherapist explaining and demonstrating beneficial physical exercises. With these videos we aim to provide participants with new inspiration and practical suggestions to increase their physical activity and exercise.

Figure 2 illustrates the intervention content and flow, including an initial group session, four nurse-led motivational counselling sessions and an optional part with physiotherapist-led sessions, the possibility of teaming up with a 'exercise-buddy' and short inspirational videos.

Figure 2. 20-week intervention period



The main setting of the intervention will be the participants' everyday lives (family, work/school, leisure-time activities). However, the Gastroenterology Department, Bispebjerg Hospital, and potentially, local municipal health centres and sports clubs will be the actual physical places for the specific intervention elements (e.g. education, counselling sessions, physiotherapist-led sessions, exercising in small communities ('exercise buddies'). As the intervention focuses on and takes place in an 'everyday life'

setting, we expect the intervention to be realistic and implementable in the gastroenterology clinic and/or the municipal health centres subsequently.

Control group

Participants randomized to the control group will be encouraged to maintain their usual lifestyle and activities. They will be expected to undergo the same baseline – and outcome assessment as the participants in the intervention group.

Outcome measures

The primary focus of the study is to investigate study feasibility and acceptability, including investigating facilitators/barriers for recruitment, acceptance of group allocation, study retention, the quality of delivery methods, intervention fidelity (project staff's fidelity to intervention manual), participants' perception of the developed intervention and the adherence to outcome assessments. Assessment of intervention fidelity and acceptability will include qualitative methods such as observations of the intervention elements and interviews with participants and project staff. The specific outcome assessments in the feasibility study will include a range of both objectively measured outcomes and self-administered questionnaires.

Objectively measured physical activity

The SENS motion®(SENS Innovation ApS) is a waterproof activity sensor (45 × 23 × 5mm, 6 g), which the participants will wear laterally on the right thigh (20). The sensor is placed in a small patch specially designed for the SENS sensor and is attached on the skin with adhesive tape. The sensor is a triaxial accelerometer, which samples at 12 Hz and registers the orientation and acceleration of the thigh. Based on this orientation and acceleration, the sensor captures seven-day, 24-hour physical activity patterns, including number of steps and the amount of daily time lying down, sitting, standing, and being active with light, moderate and high intensity, as well as specific activities such as bicycling or walking stairs (28). SENS is used primarily as a single sensor system, but a dual-sensor algorithm has been developed to enable distinction between different sedentary positions, including sitting with inclined and upright backrest. Therefore, for the present study, we expect that two sensors will be used (one placed on the thigh and one on upper back). Patients will simultaneously be asked to fill in a diary reporting what time they get up in the morning, go to work, finish work and go to sleep for the seven-day measurement period.

Self-reported physical activity and sitting time

Self-reported physical activity (light, moderate, vigorous) and sitting time at work and during leisure time will be measured by the Physical Activity Scale 2.1 (PAS 2.1) (21), a modified version of the original PAS

questionnaire, which has previously been validated against accelerometer, physical activity logs and maximum oxygen uptake (22,23). Respondents will be asked to specify number of hours and minutes in an average 24-hour day spent sitting at work and during leisure time. In addition, participants will report number of weekly hours and minutes spent in light, moderate or vigorous intensity activities.

The participants will be asked to respond to PAS 2.1 at baseline and again at the 20-week follow-up assessment. In addition, the project nurses will conduct a telephone-based mini-survey four times with each participant during the intervention period in order to monitor changes in physical activity behaviour in-between the two outcome assessment times. The survey will consist of three questions about the participant's weekly time spent on moderate to vigorous physical activity, light-intensity physical activity and sedentary behaviours.

Exercise self-efficacy

The Exercise Self-Efficacy Scale assesses an individual's beliefs in their ability to continue exercising under different circumstances (24). For instance, participants will be asked to report their belief in their own ability to engage in physical activity and exercise when it is raining/snowing, when they are tired, when they are short of time etc.

Disease-specific quality of life

The 32-item Inflammatory Bowel Disease Questionnaire (IBDQ-32)(25) is the most frequently used instrument to capture disease-specific quality of life for patients with IBD. The IBDQ-32 captures the patient's experience of IBD on four domains of functioning and well-being: 1) bowel symptoms, 2) systemic symptoms, 3) emotional function and 4) social function (25).

Fatigue

The 20-item Multi-dimensional Fatigue Inventory (MFI 20) (26) will be included to measure fatigue. MFI 20 consists of 20 statements, which classifies fatigue in five dimensions: 1) general fatigue 2) physical fatigue 3) mental fatigue 4) reduced activity 5) reduced motivation.

Pain

Participants' pain levels will be measured by the Visual Analogue Scale (VAS) (27), which transforms the subjective experience of pain to a measurable quantity. The participant indicates his or her pain by putting a mark on the line where the ends are marked with 'no pain' to 'worst imaginable pain. In addition, the participant will report from where the bodily pain locates ('pain site').

Mental health

The HADS (Hospital Anxiety and Depression Scale) questionnaire aims to measure symptoms of anxiety (HADS Anxiety) and depression (HADS Depression). The HADS questionnaire consists of seven items for depression and anxiety subscales, respectively. Scoring for each item ranges from zero to three, with three indicating highest anxiety or depression level (28)

Fecal calprotectin

Fecal calprotectin is a common stool test that is used to detect inflammation in the intestines. As such, it will be used to monitor the participants' disease activity and severity.

Serum lipids, CRP and glycosylated hemoglobin

A venous blood sample will be drawn (not fasting). Total cholesterol, high-density lipoprotein cholesterol (HDL), and triglycerides will be measured. Low-density lipoprotein cholesterol (LDL) and very low-density lipoprotein cholesterol (VLDL) will be calculated by the formulae: VLDL = Triglyceride x 0.45 and LDL = Total cholesterol − HDL + VLDL. In addition, C-reactive protein (CRP), albumin and glycosylated hemoglobin, type A1c (HbA1c) will be measured.

Blood pressure

Blood pressure will be measured, after 5 to 10 minutes of rest, 3 times at the right upper arm (average of the 3 measurements) with the participant in a sitting/lying position.

Anthropometric measures

Anthropometric measures such as height, weight and waist- and hip circumference will likewise be included in the assessments. Height is measured without shoes to the nearest centimeter; weight is measured in light clothing without shoes to the nearest 0.1 kg; waist circumference is measured midway between the lower rib margin and the iliac crest to the nearest 0.5 centimeter, without any pressure to the skin and with an unstretched tape measure; hip circumference is measured at the point yielding the maximum circumference over the buttocks to the nearest 0.5 centimeter. The tape should be held in a horizontal plane touching the skin but not indenting the soft tissue. Body mass index (BMI, kg/m2) and waist-hip ratio will be calculated.

Demographic and clinical information

In addition, information regarding demographics (e.g. sex, age, education, civil status, employment) and lifestyle (smoking and alcohol consumption) will be obtained by self-reports while data on disease location

and duration, disease severity, surgery, medical treatment and active co-morbidities in form of disease in joints, skin, pancreas, thyroid, lungs or liver and prescriptions (FMK) will be collected from Epic (Sundhedsplatformen). The researchers' direct access to the electronic patient records and retrieval of these data will be depended on signed informed consent from the relevant participant. Information on diagnosis and medical treatment is necessary for identification and screening of the participants (see in- and exclusion criteria) before an eventual signing of informed consent.

Data collection from outcome assessments

Outcome assessment will be conducted at study inclusion/baseline and repeated at end of the intervention period (20 weeks (five months) from baseline) for each of the 30 participants. Participants will complete self-administered questionnaires regarding demographics, lifestyle, physical activity, disease-specific quality of life, pain, fatigue and intrusiveness of IBD. Anthropometric measures, blood pressure, fecal calprotection test and a single blood sample will be obtained at the same time points by a project nurse. Calprotectin test and blood samples will be analyzed at Department of Clinical Biochemistry, Bispebjerg Hospital, for inflammation biomarkers and lipid status. In addition, the same project nurse will attach the SENS motion activity sensor on the participants' thigh and instruct participants how to wear the monitors 24 hours per day for seven continuous days. The activity sensors connect wirelessly to a smartphone application, and the recorded data are transmitted to the application every 10 minutes, when the smartphone is within network reach or stored on the sensor for later transmission. The raw triaxial accelerometer data are transferred automatically to a secure web server (Capital Region, Denmark) via the smartphone. During each assessment the participants will fill in a daily report of their resting and sleeping time in order to isolate their sitting time from sleeping time. After the seven-day assessment period the participants will remove the sensor and keep it until the next appointment at Bispebjerg Hospital, where they will return it to the project nurse.

Data collection from feasibility and acceptability

Regarding data on feasibility and acceptability, the intervention leader (TT) will document all components of the recruitment and screening procedure. This will include documentation of the number of invited and screened patients and reasons for exclusion or declining study participation. Acceptability and fidelity to the intervention elements and outcome assessments will be evaluated through interviews with project staff delivering the intervention and with five study participants. Furthermore, this will be monitored using a log sheet in which information on intervention progress and retention will be registered.

Data management

All data in the feasibility study will be collected and managed using an electronic case record form (eCRF), which is based on REDCap (Research Electronic Data Capture) (29), hosted at the Capital Region, Denmark. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for seamless data downloads to common statistical packages and 4) procedures for importing data from external sources. Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospitals, will act as the project owner in REDCap. All access to the server and other server maintenances will be logged. Study setup and hosting will be performed by Bispebjerg Hospital. Only authorized access to the eCRF will be possible using encrypted username and password. Roles in the system are given according to functions (project leader, study nurse etc.). All tasks performed in the eCRF are logged in an audit trail. The project leaders and authorized project staff can add data to the eCRF and will keep the eCRF current to reflect subject status during the study period. The project personnel will make a separate confidential record of personalized details (name and initials) and enrollment log on the individual participant, which is kept separately from the eCRF. Once the eCRF for a participant is completed, the authorized staff will approve the data using an electronic signature and thereby confirm the accuracy of the data recorded.

(Statistical) analyses

The primary analyses will be of feasibility outcomes. We will report the numbers of screened and eligible participants seen over the recruitment period, and the rates of retention and adherence, that is proportion of participants completing outcome assessments and receiving intervention elements (both basic and optional elements). In addition, we will ascertain data completeness of the instruments and any potential bias in the completion of follow-up data to inform the choice of instruments in a future randomized controlled trial. Also, we will use the results (standard deviations) from the objectively measured physical activity levels to determine the appropriate sample size for the later randomized controlled trial.

Descriptive statistics in the feasibility study will give insight into participants' characteristics as well as distributions and indications of change in the outcome measures. The descriptive statistics will summarize categorical data (frequencies (%)) and continuous data (medians, means (M) and standard deviations (SD)). Changes in outcome measures from baseline to end of intervention will be reported as within-group differences (M and SD) in the intervention and the control group separately and between-group differences in change will be summarized (M, SD). All analyses will be conducted using SAS software (v. 9.3; SAS Institute Inc., Cary, NC, USA).

Risks and adverse events

The SENS motion activity sensor is sealed and placed in a small patch to avoid direct contact with the skin. The participants will be encouraged to change the location of the unit or contact intervention leader (TT) if the patch comes off or if they experience skin redness or itching. In our previous studies using activity monitors on patients with rheumatoid arthritis, few cases of redness and itching were reported as the only adverse events from using the monitors along with the inconvenience of having the unit attached to thigh and/or shoulder (17). Adverse effects such as muscle soreness, joint pain, muscle cramps and increased need to rest may be expected as participants are encouraged to be more physically active.

Routine stool and blood samples are included in the study. The blood samples are taken by experienced staff and carried out in a quiet shielded room. A foreseeable risk involves the possible discomfort and small hematoma following the sampling of blood from the antecubital vein.

Ethical considerations

The study will be conducted according to the Danish Health law and the General Data Protection Law (GDPR) regarding handling of personal data. Approval by the Regional Scientific Ethical Committee of the Capital Region of Denmark will be obtained before initiation of the study. Both oral and written informed consent will be obtained before entering the study in compliance with the Declaration of Helsinki. In a patient perspective, the benefits of participating in development and testing of a physical activity intervention on health outcomes is believed to overweigh the disadvantages. The physical tests and self-reported measurements comprise no foreseeable risks for the participants. In fact, the blood sample and fecal calprotection tests are part of routine testing in the gastroenterology outpatient clinic. As the potential scientific benefits of conducting these studies outweigh the discomfort, which some participants may experience, we believe that the ethical aspects of the studies are feasible and that the overall research results may lead to individually targeted, improved health in patients with IBD and strengthened capacities in healthcare professionals.

Time Schedule

The overall project started up March 1st 2022, where the epidemiological part was initiated. The intervention part will be initiated Aug 1st 2022 and the development of the intervention was conducted in ultimo 2022/primo 2023. We expect the feasibility study (study IV) to start in October/November 2023.

	2022 Project start: March 1st				2023				2024 Project end: Dec 31st			
PART I : Epidemiological studies. March 1st 2022												
Preparation and Data management.												
Statistical analyses.												
Preparation of scientific manuscripts												
Results for interventions studies												
PART II: Intervention studies. Aug 1st 2022												
Observation, stakeholder consultations												
Co-creation, workshops, intervention development												
Conduct of feasibility study												
Preparation of scientific manuscripts												

Perspectives

The present studies will provide new and important insights into the prevalence and significance of physical activity and sedentary behavior in patients with IBD. The intervention that will be developed and tested in the feasibility study is planned to be further tested in an RCT before possible implementation in clinical practice. As a supplement to medical treatment, this intervention may potentially improve symptoms and health-related quality of life in the large group of people living with IBD.

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